



## National Rural Water Association

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**Attention:** Docket ID No. OEI-10014.

**Subject:** NRWA Comments on draft ***Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the EPA***

Dear Ms. Cummings:

The National Rural Water Association (NRWA) welcomes this opportunity to comment on the U.S. Environmental Protection Agency (EPA) draft, ***Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the EPA*** (referred to hereafter as the draft ***Guidelines***), released on May 1, 2001.

NRWA is a non-profit association representing over 22,000 rural and small drinking water systems across the nation.

NRWA's comments are provided in two sections below. First, our overall observations and main points are summarized. In the second section, the Association's three main observations and concerns are discussed in greater detail.

### **A. General Overview of NRWA Comments**

NRWA strongly endorses all efforts to ensure that high quality data -- and high quality statistical analyses and interpretations of those data -- are used by EPA (or other agencies) in making important regulatory and policy decisions or in disseminating information to the public. The quality, credibility, transparency, reproducibility, and objectivity of data and associated analyses are critical to

developing scientifically sound and economically prudent regulatory decisions in the public health and environmental policy arenas.

The NRWA's main observations and comments on the draft *Guidelines* are as follows:

1. NRWA hopes that EPA vigorously applies and enforces its draft *Guidelines* in the risk assessment area, with special attention to the provision of central estimates of risks rather than risk and benefit estimates that are inflated by the use of upper bounds and precautionary assumptions.
2. NRWA is very concerned that the administrative review procedures provided in EPA's draft *Guidelines* will be insufficient to address the persistent and considerable data quality problems experienced by NRWA and other stakeholders. These data quality problems pertain to the lack of clear foundation, replicability, or transparency in EPA regulatory analyses of the costs and benefits of drinking water standards (e.g., Maximum Contaminant Levels, MCLs), as issued by EPA under the Safe Drinking Water Act Amendments of 1996 (SDWAA).

NRWA strongly believes that the complaint review and resolution process proposed by EPA is insufficient to properly address this important problem. A stronger set of procedures is necessary to suitably provide impartial, independent review and (as necessary) effective remedy.

- ▶ The complaint review and resolution process should not automatically exclude issues that have been (or could have been) raised as part of the public comment process associated with EPA rulemaking procedures.
  - Unfortunately, repeated experience reveals that even where such issues have been raised in public comments, the Agency's responses often have not provided sufficient recognition or resolution of transparency or reproducibility problems, data quality deficiencies, and objectivity concerns.
  - A lack of transparency and other data quality problems persist in EPA regulatory analyses the Association has reviewed, despite the fact that NRWA and other stakeholders have submitted numerous comments within the rulemaking process regarding these deficiencies.
- ▶ The review process should be conducted and governed by a body more independent and neutral than the manager (e.g., Division Director, Office Director, or Assistant Administrator) of the immediate EPA office that "owns" the data and issued the information or rule in question.

## **B. Detailed Discussion of NRWA's Primary Concerns and Comments**

Under Section 515(a) of the Treasury and General Government Appropriations Act for Fiscal year 2001 (Public Law 106-554; H.R. 5658), Congress directed the Office of Management and Budget (OMB) to issue government-wide guidelines to ensure and maximize the "quality, objectivity, utility, and integrity of information (including statistical information) disseminated" or used by federal agencies in pursuing their missions. OMB issued its "Guidelines" (Federal Register, p8452, February 22, 2002), through which it directed each relevant federal Agency to develop its own information quality guidelines within one year. EPA released its draft *Guidelines* on May 1, soliciting public comment through May 31, 2002.

### **NRWA Believes that Better Administrative Procedures Are Needed to Promote Data Quality and Transparency, and that EPA's draft *Guidelines* Need to be Improved to Accomplish this Important Objective**

A key component of enforcing the mandate that Agencies conduct credible and objective risk assessments and benefit-cost analyses is to provide effective administrative procedures that ensure that suitable data and methods are applied in these analyses. Toward that end, NRWA supports efforts by OMB and EPA to promote transparency and ensure data quality. Accordingly, NRWA has reviewed with interest EPA's draft *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the EPA*.

NRWA and other stakeholders have been frustrated over the past several years with the lack of transparency and reproducibility in EPA's analyses of the benefits and costs of proposed and final rulemakings under the SDWAA. NRWA and other stakeholders have been further frustrated by EPA's general unresponsiveness to constructive data quality, transparency, and reproducibility critiques. These critiques have been offered in many settings, including submissions as part of the public comments provided by NRWA, AWWA, and other relevant entities as part of rulemaking procedures. Hence, NRWA strongly believes that a critical element in the *Guidelines* is to develop and implement an effective administrative procedure to provide a fair and independent review of data quality issues that have not been suitably addressed by EPA in the Agency's response to public comments.

Specific problems and concerns that NRWA has regarding EPA's proposed data quality guidelines are as follows:

**Problem #1: The risk assessment portions of the *Guidelines* need to be effectively applied and rigorously enforced to ensure that policy makers (and stakeholders) have accurate information upon which to base their decisions (*Risk Assessment*, section 4.3 of the *Background and Discussion*, and section 3.4 of the *Draft Guidelines*)**

Risk assessment data are clearly influential information because they typically serve as a cornerstone for EPA's regulatory decisions (e.g., how stringently to set an MCL or other standard), or whether EPA decides whether or not to regulate a compound at all. Risk assessments also serve as a core element in the benefit-cost analyses (BCA) that are mandated under the SDWAA as a basis for determining the suitable stringency of an MCL (i.e., risk assessments are used to quantify the public health benefits that are the cornerstone of the Health Risk Reduction and Cost Analyses (HRRCA), as mandated per Section 1412(b)(3)(C) of the SDWAA).

NRWA is pleased that EPA (and OMB) are seeking to extend the SDWAA's risk assessment provisions to other risk assessment applications. NRWA endorses the broader applicability of the SDWAA principles as stated in Section 1412(b)(3) of the Act. The Association also is pleased that EPA's draft *Guidelines* emphasize that the SDWAA provisions call for the use of "best available, peer reviewed science" and "data collected by accepted methods or best available methods."

Also mentioned in the draft *Guidelines* (at line 669) is an especially important Congressional mandate from Section 1412 of the law, pertaining to the use of "expected ... or central estimate of human health risk." As stated in the SDWAA (emphasis added):

- ▶ "...specify, to the extent practicable ...(ii) the expected risk or central estimate of risk" ... as well as "(iii) appropriate upper-bound and lower-bound estimates of risk"...and have "(iv) each significant uncertainty identified in the process of the assessment of public health effects..." [1412(b)(3)(B)].
- ▶ consider within the mandated benefit-cost comparison "...health risk reduction benefits for which there is a factual basis ...that such benefits are likely to occur as the result of treatment to comply..."[ 1412(b)(3)(C)].

These SDWAA statutory directives clearly indicate that EPA should develop and consider risk and benefit estimates that reflect the *most likely* outcomes from a potential regulation (such as an MCL). It is vital that these principles of using "central estimates" be well highlighted and universally enforced as part of EPA's implementation of the *Guidelines*. NRWA hopes that EPA fully adheres to these statutory principles and vigorously enforces these "central estimate" provisions of its draft *Guidelines*.

*The Guidelines* and the SDWAA's statutory language both acknowledge that uncertainties will exist and that upper and lower bounds need to be presented and taken into consideration. However, the statutory language also is explicit that Congress intended EPA to provide estimates of *expected* (central estimate) risks when comparing benefits to costs and making regulatory decisions. This means that risk assessments as traditionally developed (i.e., embodying numerous precautionary assumptions) need to be re-interpreted to reflect *expected* risks for a benefit-cost analysis (rather than using, for example, risk estimates derived to be safe with a margin of error - such that the estimated risks levels are likely to be over-stated).

EPA itself conveys a similar philosophy in its *Guidelines for Preparing Economic Analyses* (U.S. EPA, 2000a). Economic Analyses (EAs) are developed by EPA for all “significant” rulemakings (not just drinking water), and are submitted for review to the OMB in accordance with Executive Order 12866 (Federal Register, October 4, 1993). EAs contain assessments of the benefits and costs of the options under consideration in a given rulemaking. EPA’s *Guidelines for Preparing Economic Analyses* explicitly state that benefit-cost outcomes should be presented “based on expected or most plausible values” and accompanied by sensitivity analyses to reflect the impact of key assumptions and uncertainties embedded in the analysis (p. 27), and that “uncertainties should be explored through the use of expected values supplemented by upper and lower bounds” (p. 176).

OMB has also issued similar directives in its recommended approaches for developing benefit-cost analyses to support regulatory decision-making. *The Office’s Guidelines to Standardize Measures of Costs and Benefits and the Format of Accounting Statements* (OMB, March 2000) directs federal agencies to “...calculate the benefits (including benefits of risk reductions) that reflect the full probability distribution of potential consequences ...and include upper and lower bound estimates as complements to central tendency ...estimates” (p. 9). The OMB guidelines further state that “some estimate of central tendency - such as the mean or median - should be used” for developing benefit-cost comparisons and decision-making (p. 15).

Therefore, it is clear from the governing federal statute - as well as in the relevant federal agency guidelines - that standard setting and other risk management activities should be based on central, most likely estimates of risks. Plausible upper and lower bounds of risk also should be used to reflect uncertainties (and, if available, probability distributions are preferred to bounds). However, the application of risk assessments that embody the typical array of precautionary assumptions will not furnish the necessary “most likely” estimates of risks that are necessary and appropriate for BCA and standard setting.

Accordingly, NRWA believes that EPA’s *Guidelines* should clearly establish that central estimates of risks (and associated benefits) be provided to policy makers as the basis for considering their decisions where risk assessments are used as part of the regulatory decision-making process. This information should also be made publicly available so that stakeholders can also see the transparent impact of precautionary assumptions on risk estimates. NRWA recognizes that there are instances in which risk assessments might suitably embody a moderate degree of precaution (e.g., when defining a level at which zero risk is anticipated); however, NRWA strongly believes that precautionary assumptions must be removed from risk assessment data and interpretations when used in a benefits analysis context.

Further, as part of its efforts to ensure data quality, replicability, and transparency, EPA should clearly and explicitly indicate what precautionary assumptions and uncertainty factors are embodied in any risk assessment it generates and/or uses. As a matter of policy, EPA also should clearly indicate the quantitative impact these assumptions, safety factors,

and statistical procedures have -- both individually and collectively -- on the numerical risk assessment and benefits results.

**Problem #2: Excluding reviews of data quality issues associated with regulatory actions leaves stakeholders with no recourse (*Correction of Information, section 5.2 of the Background and Discussion, and section 5.4 of the Draft Guidelines*)**

NRWA notes with great concern that EPA's draft *Guidelines* state that data quality reviews related to rulemakings will NOT generally be allowed under the information review process. EPA's rationale is that the public comment periods provide suitable venue for previously airing these concerns. NRWA strongly disagrees.

The problem is that EPA's regulatory analyses are often too complex and so lacking in transparency that it is not possible fully address these issues within the limited public comment periods allotted (at least that is NRWA's experience with drinking water regulations). In addition, EPA has often chosen to acknowledge but then ignore in substance the data quality, replicability, and transparency issues raised in submitted public comments. NRWA and other stakeholders have no administrative process through which to seek recourse in such situations where EPA evades responding in a constructive and substantive manner to data quality and related comments.

The General Accounting Office (GAO) critique of the EPA's radon rule cost estimates is revealing in terms of the potential limits of relying only on the comment period to effectively raise and rectify data quality issues (GAO, *Revisions to EPA's Cost Analysis for the Radon Rule Would Improve its Credibility and Usefulness*, February 2002). GAO had more than 6 months to review and critique EPA's cost analysis. GAO also was provided with ample access to EPA staff and materials with which to facilitate their review (GAO also had the benefit of detailed critiques submitted by various stakeholders as part of the public comment period). Even with ample time, access, and information, GAO found EPA's analysis lacking in transparency and replicability (along with other shortcomings). For a stakeholder organization like NRWA, that has to respond with critiques within an official 60 day public comment period, the problem is greatly magnified. Simply put, there is no available mechanism to have real data quality and replicability problems addressed constructively if the Agency opts to be dismissive through its response to comments.

The public comment period and comment response procedures have proven to be ineffective as a means to rectify legitimate and substantiated concerns about data quality and replicability. There is a clear need to have an open and constructive administrative review process on data quality and transparency issues, regardless of whether the issue could have been (or was) previously raised in rulemaking-related comment periods. In particular, there is a need for a process through which dismissive responses to such public comments can be reviewed and rectified.

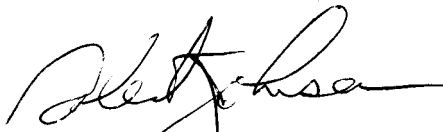
**Problem #3: The Review Process should be governed by a more independent and neutral third party** (*Correction of Information, section 5.1 of the Draft Guidelines, and the section on Complaint Resolution in the Request for Comments*).

The review process should be conducted and governed by a body more independent and neutral than the manager of the immediate EPA program office that “owns” the data and issued the information or rule in question. Furthermore, having the appeals process be governed by the Assistant (or Regional) Administrator for the program office that owns the data is also problematic in that it creates a perceived (and possibly real) bias toward supporting the program that they are managing.

NRWA suggests that an independent panel be established for the purpose of complaint resolution and any subsequent appeals. Such a body might be akin to or part of the Science Advisory Board, or similar to the model represented by the Environmental Appeals Board as a process for conflict resolution. In addition, the Office of Environmental Information (and the Agency’s Chief Information Officer) should play a more critical leadership role in the review process (both for initial complaint resolution and any subsequent appeals) rather than the program offices and their respective Assistant or Regional Administrators.

Thank you for your attention to these comments. NRWA looks forward to the Agency’s consideration of these comments as it works towards finalizing the *Guidelines*.

Sincerely yours,



Robert Johnson  
Chief Executive Officer